II. REMARKS

Claims 1-7 and 10-29 are pending stand rejected under 35 U.S.C. §§ 112, first and second paragraphs, 102 and 103.

As discussed with Examiner Li during the telephone conference of February 25, 2003, the claims have been amended herein to indicate that the immunogen is encoded by a sequence carried on a plasmid, as described throughout the specification as filed. In addition, the term BLC has been amended to refer to B lymphocyte chemoattractant, as described for example on page 10, line 23. Certain dependent claims have been amended to reflect the changes made to the independent claims. These amendments are made to solely to expedite prosecution and Applicant reserves the right to file a continuation application directed to the subject matter of the original claims at any time during the pendency of this application. No new matter has been added as a result of these amendments and entry thereof is respectfully requested.

In view of the foregoing amendments and following remarks, Applicant respectfully requests reconsideration of the restriction requirement and of the application.

Drawings

Applicant acknowledges that formal drawings are required and they are submitted herewith.

35 U.S.C. § 112, First Paragraph, Enablement

Claims 11-29 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification as filed. (Office Action, pages 2-3). It is maintained that the specification fails to provide evidence that chemokines such as BLC would induce an antibody response. (Office Action, page 3). In addition, it is maintained that one of the references cited in the previous Office Action, Gunn et al, was not addressed by Applicant. (Office Action, page 3).

As discussed during the telephone conference of February 25, 2003, the specification provides a clear example of enhanced antibody production when a chemokine (BLC) is administered with a viral immunogen. (See, Example 2). In particular, Example 2 details how BLC significantly enhances an antibody response when administered with a plasmid encoding an HIV gag immunogen. It has long been known to those working in this field that administration of HIV gag antigens alone generates only weak antibody responses. In Example 2, Applicant conclusively demonstrates that BLC significantly enhances production of anti-gag antibodies. (See, Figure 5). In other words, Applicant's specification provides clear evidence that BLC enhances the generation of antibodies directed against an antigen that does not usually generate meaningful antibody responses. Simply put, the specification clearly satisfies the requirement with regard to the methods of enhancing immune responses as set forth in claims 11-29.

Turning now the statement that Gunn was not addressed in the previous response, Applicant directs the Examiner's attention to page 5 of the Response submitted on August 19, 2002. Here, Applicant noted that Gunn's teachings regarding BLC's and migration of T-cells is not relevant to pending claims 11-29. Whereas the pending claims are directed to methods of enhancing immune responses, Gunn focuses only on migration of T-cells and the chemoattractant properties of BLC. Nothing in Gunn's disclosure establishes unpredictability of the claimed methods. Indeed, Applicant's disclosure clearly indicates that chemokines (such as BLC) act as attractants for one or more very specific molecules. (See, *e.g.*, page 4, lines 3-12). At the same time, Applicant's disclosure is clear that the attractant characteristics of a particular chemokine is not necessarily correlated with the claimed compositions or methods of enhancing immune responses. In other words, Applicant has demonstrated that chemokines can enhance immune responses regardless of what molecules they are known to attract. Thus, contrary to the Examiner's assertion, Gunn is not pertinent to the instant enablement inquiry.

Still further evidence that chemokines do in fact enhance antibody responses when administered with viral immunogens is attached hereto as Exhibit A. This publication (Kim et al. (1998) *Am. Soc. Clinical Invest.* 102(6):1112-1124) establishes that following co-administration of DNA immunogens and chemokines, both humoral and cellular responses were enhanced. (See, *e.g.*, Kim, Abstract). MIP-1α, for example, was found to be a "strong expander of antibody response." (See, Kim, page 116, right column and Figure 5A). This reference demonstrates that the specification as filed fully enables claims encompassing multiple routes of delivery.

In sum, Applicant has provided ample factual evidence that demonstrates that the specification enables the pending claims throughout their scope. For the all the foregoing reasons, Applicant submits that the specification fully enables the claims and respectfully requests withdrawal of this rejection.

35 U.S.C. § 112, Second Paragraph

The Examiner has rejected the claims under 35 U.S.C. §112, second paragraph, as allegedly indefinite in their recitation of "DNA immunogen" and "BLC." (Office Action, page 3-4).

Applicant thanks the Examiner for the suggested alternatives and have incorporated these suggestions by amendment herein. Accordingly, these rejections have been obviated.

35 U.S.C. § 102(e)

Claims 11-13, 16, 17, 21, 25 and 27-29 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,846,546 (hereinafter "Hurwitz"). Claims 11-13, 16, 17, 21, 23-29 stand rejected as allegedly anticipated by U.S. Patent No. 6,355,247 (hereinafter

"Selby"). Claims 11-13, 16, 17, 21, 27 and 29 stand rejected as allegedly anticipated by U.S. Patent No. 6,383,774 (hereinafter "Chandrashekar") in view of Hurwitz. (Office Action, page 8). Hurwitz is cited for allegedly disclosing a method comprising administering to a mammal a chemokine and a DNA immunogen. (Office Action, page 4). Selby is cited for allegedly disclosing a chemokine and a DNA immunogen. (Office Action, page 6). Chandrashekar is cited for allegedly teaching an immunogenic composition comprising a nucleic acid encoding a parasitic immunogen. (Office Action, page 8).

Because neither Hurwitz, Selby nor Chandrashekar disclose each and every element of pending claims 11-29, Applicant traverses the rejections and supporting remarks.

Pending claims 11-29 are directed methods in which the immunogen is administered as a plasmid containing a sequence encoding the immunogen. Both Hurwitz and Selby disclose only viral vectors. Accordingly, there is not identity between the methods of claims 11-29 and the disclosures of Hurwitz and Selby and, accordingly, anticipation cannot be established.

Turning to the rejection based on Chandrashekar, Applicant notes that is axiomatic that anticipation requires that a single source contain all the essential elements of the claim. Only if the single source is ambiguous can extrinsic evidence be used to explain the reference. *Scripps Clinic,* 18 USPQ2d at 1010 (Fed. Cir. 1991). Here, the Office cannot base an anticipation rejection on Chandrashekar, which unambiguously fails to disclose all the essential elements of the claims.

Therefore, withdrawal of the rejections based on 35 U.S.C. 102 is respectfully requested.

35 U.S.C. § 103

Claims 1-8, 10-21 and 23-29 stand rejected as allegedly obvious over Hurwitz and Selby and in further view of U.S. Patent No. 6,214,540 (hereinafter "DeVico"). Hurwitz and Selby are cited as above. DeVico is cited for teaching the use of chemokines for HIV therapy using chemokines. (Office Action, page 6). Further, although rejection of claims 11-13, 16, 17, 21, 27 and 29 over Chandrashekar in view of Hurwitz is purportedly made under 102(e), the rejection appears in the 103 section of the Office Action and is phrased as an obviousness rejection, and, accordingly, Applicant addresses the rejection again below.

As a threshold matter, Applicant submits that Selby is not properly cited under 103(a). As set forth in 103(c), 102(e) references (the U.S. Patent to Selby), shall not preclude patentability under 103 where the subject matter and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to the same entity. Here, both Selby and the application at hand were subject to assignment to Chiron Corporation and, accordingly, Selby is not a proper 103(a) reference.

In any event, none of the cited references suggest compositions comprising BLC and a DNA immunogen, as recited in claims 1-8 and 10. Accordingly, no combination of these references renders these claims obvious.

Similarly, there is no combination of cited references that renders the pending method claims obvious. Nowhere do Hurwitz, Selby, Chandrashekar or DeVico actually describe methods using plasmids, as claimed by Applicant. Indeed, as noted above, Hurwitz and Selby relate solely to viral vectors and there is no suggestion in any of the references to use plasmids comprising sequences encoding immunogens. Likewise, there is absolutely no suggestion in Chandrashekar to use viral immunogens and no combination of Chandrashekar's parasitic immunogens and Hurwitz's viral vectors that would lead one of skill in the art to the claimed methods. Accordingly, because there is no teaching or suggestion within the references to arrive at any of the claimed subject matter, withdrawal of the rejections is respectfully requested.

Double Patenting

In view of the foregoing amendments to the claims, the provisional obviousness-type double patenting rejection based on Selby has been obviated and withdrawal of this rejection is respectfully requested.

III. CONCLUSION

For the reasons state above, Applicant respectfully submits that the pending claims define an invention which is novel and fully enabled and described by the specification. Accordingly, Applicant requests that the rejection of the claims be withdrawn, and that the application proceed to allowance. Please direct all further communications regarding this application to:

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